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CANAL HEARING DEVICE WITH TUBULAR INSERT

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Background of the Invention

A. Technical Field

The present invention relates to hearing devices, and, more particularly, to miniature hearing devices that are deeply positioned in the ear canal for improved energy efficiency, sound fidelity, and inconspicuous wear.

B. Description of the Prior Art

Brief Description of Ear Canal Anatomy

The external acoustic meatus (ear canal) is generally narrow and tortuous as shown in the coronal view in **Fig. 1**. The ear canal **10** is approximately 25 mm in length from the canal aperture **17** to the tympanic membrane **18** (eardrum). The lateral (away from the tympanic membrane) part, a cartilaginous region **11**, is relatively soft due to the underlying cartilaginous tissue. The cartilaginous region **11** of the ear canal **10** deforms and moves in response to the mandibular (jaw) motions, which occur during talking, yawning, eating, etc. The medial (towards the tympanic membrane) part, a bony region **13** proximal to the tympanic membrane, is rigid due to the underlying bony tissue. The skin **14** in the bony region **13** is thin (relative to the skin **16** in the cartilaginous region) and is more sensitive to touch or pressure. There is a characteristic bend **15** that roughly occurs at the bony-cartilaginous junction **19**, which separates the cartilaginous **11** and the bony **13** regions. The magnitude of this bend varies

significantly among individuals. The internal volume of the ear canal between the aperture **17** and tympanic membrane is approximately 1 cubic centimeter (cc).

A cross-sectional view of the typical ear canal **10** (**Fig. 2**) reveals generally an oval shape and pointed inferiorly (lower side). The long diameter ($\mathbf{D_L}$) is along the vertical axis and the short diameter ($\mathbf{D_S}$) is along the horizontal axis. Canal dimensions vary significantly among individuals as shown below in the section titled Experiment A.

Physiological debris **4** in the ear canal is primarily produced in the cartilaginous region **11**, and includes cerumen (earwax), sweat, decayed hair, and oils produced by the various glands underneath the skin in the cartilaginous region. There is no cerumen production or hair in the bony part of the ear canal. The ear canal **10** terminates medially with the tympanic membrane **18**. Laterally and external to the ear canal is the concha cavity **2** and the auricle **3**, both also cartilaginous.

Several types of hearing losses affect millions of individuals. Hearing loss particularly occurs at higher frequencies (4000 Hz and above) and increasingly spreads to lower frequencies with age.

The Limitations of Conventional Canal Hearing Devices.

Conventional hearing devices that fit in the ear of individuals generally fall into one of 4 categories as classified by the hearing aid industry: (1) Behind-The-Ear (BTE) type which is worn behind the ear and is attached to an ear mold which fits mostly in the concha; (2) In-The-Ear (ITE) type which fits largely in the auricle and concha cavity areas, extending minimally

into the ear canal; (3) In-The-canal (ITC) type which fits largely in the concha cavity and extends into the ear canal (see Valente M., *Strategies for Selecting and Verifying Hearing Aid Fittings*. Thieme Medical Publishing. pp. 255-256, 1994), and; (4) Completely-In-the-Canal (CIC) type which fits completely within the ear canal past the aperture (see Chasin, M. *CIC Handbook*, Singular Publishing ("Chasin"), p. 5, 1997).

The continuous trend for the miniaturization of hearing aids is fueled by the demand for *invisible* hearing products in order to alleviate the social stigma associating hearing loss with aging and disability. In addition to the cosmetic advantage of canal devices (ITC and CIC devices are collectively referred to herein as canal devices), there are actual acoustic benefits resulting from the deep placement of the device within the ear canal. These benefits include improved high frequency response, less distortion, reduction of feedback and improved telephone use (Chasin, pp. 10-11).

However, even with these significant advances leading to the advent of canal devices, there remains a number of fundamental limitations associated with the underlying design and configurations of conventional canal device technology. These problems include: (1) oscillatory (acoustic) feedback, (2) custom manufacturing and impression taking, (3) discomfort, (4) occlusion effect and, (5) earwax. These limitations are discussed in more detail below.

(1) *Oscillatory feedback* occurs when leakage (arrows **32** and **32'** in **Fig. 3**) from sound output **30**, typically from a receiver **21** (speaker), occur via a leakage path or a vent **23**.

The leakage (**32'**) reaches a microphone **22** of a canal hearing device **20** causing sustained oscillation. This oscillatory feedback is manifested by "whistling" or "squealing" and is not only annoying to hearing aid users but also interferes with their communication. Oscillatory feedback is typically alleviated by tightly occluding (sealing) the ear canal. However, due to imperfections in the custom manufacturing process (discussed below) or to the intentional venting incorporated within the hearing device (also discussed below) it is often difficult if not impossible to achieve the desired sealing effect, particularly for the severely impaired who require high levels of amplification. Oscillatory feedback primarily typically occurs at high frequencies due to the presence of increased gain at these frequencies.

(2) *Custom manufacturing and impression taking*: Conventional canal devices are custom made according to an impression taken from the ear of the individual. The device housing **25 (Fig. 3)**, known as *shell*, is custom fabricated according to the impression to accurately assume the shape of the individual ear canal. Customizing a conventional canal device is required in order to minimize leakage gaps, which cause feedback, and also to improve the comfort of wear. Custom manufacturing is an imperfect process, time consuming and results in considerable cost overheads for the manufacturer and ultimately the hearing aid consumer (user). Furthermore, the impression taking process itself is often uncomfortable for the user.

(3) *Discomfort*, irritation and even pain frequently occur due to canal abrasion caused

by the rigid plastic housing **25** of conventional canal devices **20**. This is particularly common for canal devices that make contact with the bony region of the ear canal. Due to the resultant discomfort and abrasion, hearing devices are frequently returned to the manufacture in order to improve the custom fit and comfort (Chasin, p. 44). "The long term effects of the hearing aid are generally known, and consist of atrophy of the skin and a gradual remodeling of the bony canal. Chronic pressure on the skin lining the ear canal causes a thinning of this layer, possibly with some loss of skin appendages" (Chasin, p. 58).

(4) The *occlusion effect* is a common acoustic problem caused by the occluding hearing device. It is manifested by the perception of a person's "self-sounds" (talking, chewing, yawning, clothes rustling, etc) being loud and unnatural compared to the same sounds with the open (unoccluded) ear canal. The *occlusion effect* is primarily due to the low frequency components of self-sounds and may be experienced by plugging the ears with fingers while talking for example. The *occlusion effect* is generally related to sounds resonating within the ear canal when occluded by the hearing device. The occlusion effect is demonstrated in **Fig. 3** when "self-sounds" **35**, emanating from various anatomical structures around the ear (not shown), reach the ear canal **10**. When the ear canal is occluded, a large portion of self-sounds **35** are directed towards the tympanic membrane **18** as shown by arrow **34**. The magnitude of "occlusion sounds" **34** can be reduced by incorporating an "occlusion-relief vent" **23** across the canal

device **30**. The occlusion-relief vent **23** allows a portion of the "occlusion sounds" **35** to leak outside the ear canal as shown by arrow **35'**.

The *occlusion effect* is inversely proportional to the residual volume of air between the occluding hearing device and the tympanic membrane. Therefore, the *occlusion effect* is considerably alleviated by deeper placement of the device in the ear canal. However, deeper placement of conventional devices with rigid enclosures is often not possible for reasons including discomfort as described above. For many hearing aid users, the *occlusion effect* is not only annoying, but is often intolerable leading to discontinued use of the canal device.

(5) Earwax build up on the receiver of the hearing device causing malfunction is well known and is probably the most common factor leading to hearing aid damage and repair (Oliveira, et al, *The Wax Problem: Two New Approaches*, The Hearing journal, Vol. 46, No. 8).

The above limitations in conventional canal devices are highly interrelated. For example, when a canal device is worn in the ear canal, movements in the cartilaginous region "can lead to slit leaks that lead to feedback, discomfort, the occlusion effect, and 'pushing' of the aid from the ear" (Chasin, pp. 12-14). The relationship between these limitations is often adverse. For example, occluding the ear canal tightly is desired on one hand to prevent feedback. However, tight occlusion leads to the occlusion effect described above. Attempting to alleviate

the occlusion effect by a vent **23** provides an opportunistic pathway for output sound **30** (**Fig. 3**) to leak back (arrows **32** and **32'**) and cause feedback. For this reason alone, the vent **23** diameter is typically limited in CIC devices to .6 - .8 mm (Chasin, pp. 27-28).

Review of state-of the-art in related hearing device technology

Ahlberg, et al and Oliviera, et al in US patents 4,880,076 and 5,002,151 respectively, disclose an earpiece with sound conduction tube having a solid compressible polymeric foam assembly. The retarded recovery foam must first be compressed prior to its insertion into the ear canal to recover and seal within. However, a compressible polymeric foam can be uncomfortable and irritating to the ear canal after recovering (i.e., being decompressed). Furthermore, many impaired individuals do not possess the required manual dexterity to properly compress the foam prior to insertion in the ear canal.

Sauer et al., in US patent 5,654,530, disclose an insert associated with an ITE device (Fig 1 in Sauer) or a BTE device (Fig. 2 in Sauer). The insert is a "sealing and mounting element" for a hearing device positioned concentrically within the insert. Sauer's disclosure teaches an insert for ITEs and BTEs; it does not appear to be concerned with inconspicuous hearing devices that are deeply or completely inserted in the ear canal, or with delivering sound and sealing in the bony region of the canal.

Garcia et al., in U.S. patent 5,742,692 disclose a hearing device (10 in Fig. 1 of Garcia) attached to a flexible seal (collar 30) which is fitted in the bony region of the ear canal. The device 10 is substantially positioned in the cartilaginous region along with the collar 30, which

is partially positioned over the housing. It is not clear how the disclosed device with its contiguous housings and seal configuration can fit comfortably and deeply in many small and contoured canals.

Voroba et al in US patent 4,870,688 discloses a mass-producible hearing aid comprising a solid shell core (20 in Figs. 1 and 2 of Veroba) which has a flexible covering 30 affixed to the exterior of the rigid core 20. The disclosed device further incorporates a soft resilient bulbous tubular segment 38 for delivering sound closer to the tympanic membrane and sealing within. Similarly, it is unlikely for this contiguous device/tubular segment to fit comfortably and deeply in many small and contoured canals.

None of above inventions addresses the occlusion effect other than by the conventional vent means, which are known to adversely cause oscillatory feedback.

McCarrell, et al, Martin, R., Geib, et al., Adelman R., and Shennib, et al., in US patents 3,061,689, RE 26,258, 3,414,685, 5,390,254, and 5,701,348, respectively, disclose miniature hearing devices with a receiver portion flexibly connected to a main part. Along with various accessories including removable acoustic seals, these devices have the advantage of fitting a variety of ear canal sizes and shapes thus are mass-producible in principle. However, the flexible or articulated receiver portion in these devices requires flexible mechanical and electrical connections, which result in added cost and reduced reliability compared with conventional devices which comprise instead immobile receivers contained in a singular rigid housing. Furthermore, by incorporating a seal mechanism concentrically over a rigid receiver, or a rigid receiver section, the compressibility of the seal, regardless of its compliance, is

severely limited by the rigid core section which has a substantial diameter compared with the ear canal.

Ward et al., in US patents 5,031,219 and 5,201,007, disclose a sound conduction tube (60 in Ward) for conveying amplified sound to the ear canal within the bony region in close proximity to the tympanic membrane (30). The invention also comprises a "flexible flanged tip" (70), essentially a seal, for acoustically sealing in the bony region. Ward et al. state two main objectives, viz.: "To assure proper operation of the present invention, the hearing aid should [1] neither prevent unamplified sound received at the ear from entering the ear canal, [2] nor should it contact a substantial portion of the skin lining the ear canal" (lines 32-36 col. 4 in the '219 patent and lines 37-41 col. 4 in the '007 patent). The present applicants have concluded that these limitations cause serious disadvantages for practical implementation in canal hearing devices. First, unamplified sound is allowed to freely enter the ear canal which also allows amplified sound in the bony region, which partially leaks into the cartilaginous region, to feed back to the microphone of the device and cause oscillatory feedback. This occurs because some level of leakage is always present through any acoustic barrier. Second, the contact area of the seal with the ear canal is minimized (see Figs. 1 and 5A-5F in '219 and '007, and the recital "it has been found that a suitable edge 72 thickness is approximately .05 to 2 millimeters."), so that adequate sealing along this small contact area is not possible without exerting considerable pressure on the ear canal. This is particularly problematic for canal devices having a microphone relatively in close proximity to leakage in the open ear canal as suggested and shown in the figures.

Although Ward et al. briefly mention potential applications of their devices for canal devices (lines 22-26 col. 4 in '219 and lines 27-31 col.4 in '007), the practical application is limited to BTE hearing aids with microphones far and away external to the ear canal (91 in Fig. 3. in both the '219 and '007 patents).

It is a principal objective of the present invention to provide a highly inconspicuous hearing device.

A further objective is to provide a hearing device which comfortably delivers amplified sound in the bony region in close proximity to the tympanic membrane.

Another objective is to provide an acoustic system in which acoustic sealing is maximized for prevention of feedback while simultaneously minimizing occlusion effects.

Still another objective is to improve the frequency response of delivered sound, particularly at higher frequencies while reducing occlusion sounds particularly at lower frequencies.

Yet another objective is to provide a mass-producible hearing device design which does not require custom manufacturing or individual ear canal impression.

Unlike the prior art, the present invention is not concerned with allowing external unamplified sounds to enter the ear canal.

Summary of the Invention

The invention provides a canal hearing device with a dual acoustic seal system for preventing oscillatory feedback while simultaneously channeling occlusion sounds away from the eardrum, thus minimizing occlusion effects. The two-part canal hearing device comprises a generic main module and an elongated tubular insert for conducting sound from the main module to the tympanic membrane and for sealing within the ear canal. The main module is positioned in the cartilaginous portion of the ear canal, either in the medial concha area or medially past the aperture of the ear canal. The replaceable tubular insert extends medially from the cartilaginous region into the bony portion of the ear canal. The tubular insert comprises a flexible sound conduction tube, a primary seal medially positioned in the bony region, and a secondary seal laterally positioned in the cartilaginous region. The sound conduction tube is radially flexible and has a diameter substantially smaller than that of the ear canal, for ease of insertion within. The primary and secondary seals are generally cylindrically hollow and are coaxially concentrically positioned over the sound conduction tube for making a substantial sealing contact with the walls of the ear canal thus distributing and minimizing contact pressure. The primary seal and the tympanic membrane form a first chamber of air-space therebetween. The primary and secondary seal also form a second chamber therebetween. The secondary seal, although providing additional acoustic sealing benefits for the prevention of feedback, also has a relatively large vent, compared to the pressure vent associated with the primary seal. This provides a path of least resistance towards outside the ear for occlusion sounds generated by the individual wearing the hearing device.

In a preferred embodiment of the invention, the tubular insert is disposable and comprises a coiled skeletal frame to provide high radial flexibility while maintaining sufficient axial rigidity for comfortable, kink-resistance, and consistent placement within the ear canal.

In another embodiment of the invention, the tubular insert comprises only a primary seal system positioned in the bony region while the secondary seal is provided within the main module fitted in the ear canal. Similarly, the main module is appropriately vented to provide a path of least resistance for occlusion sounds while providing additional sealing for the prevention of oscillatory feedback.

Brief Description of the Drawings

The above and other objectives, features, aspects and attendant advantages of the invention will become further apparent from a consideration of the following detailed description of the presently contemplated best mode of practicing the invention, with reference to certain preferred embodiments and methods thereof, in conjunction with the accompanying drawings, in which:

Fig.1 is a side view of the human ear canal, described above;

Fig. 2 is a cross sectional view of the typical ear canal;

Fig. 3 is a side view of the ear canal occluded with conventional canal device positioned therein, described above;

Fig. 4 is a side view of a hearing device according to a preferred embodiment of the invention comprising a main module and a tubular insert having a dual seal system, in which

occlusion mitigation via occlusion-relief vent is shown;

Fig. 5 shows a tubular insert with flange-shaped primary and secondary seals and sound conduction tube connecting to a receiver sound port via a side-slide connection mechanism;

Fig. 6 shows a tubular insert with alternate configurations for primary seal, secondary seal, pressure vent, and occlusion relief vent;

Fig. 7 shows a tubular insert with alternate attachment concentrically positioned over the receiver section of the main module, and with a coiled skeletal frame within a sound conduction tube;

Fig. 8 shows circular and longitudinal support elements within the sound conduction tube of the tubular insert;

Fig. 9 shows helical support element within sound conduction tube of tubular insert;

Fig. 10 shows a multichannel tubing within sound conduction tube for separately conducting multiple channels of sounds to the tympanic membrane;

Fig. 11 shows a multichannel tubing for separately conducting sound medially to the tympanic membrane and occlusion sounds laterally away from the tympanic membrane;

Figs. 12A-C shows various cross-sectional shapes of seals: **A.** circular, **B.** elliptical, and **C.** oval and inferiorly pointed;

Fig. 13 shows an alternate configuration of the main module essentially suspended by the secondary seal with minimal or no contact with the walls of the ear canal;

Fig. 14 is an alternate embodiment of the invention with the body of the main module providing the secondary sealing and occlusion venting incorporated within;

Fig. 15 shows a detailed view of a mushroom shaped tubular insert having only a primary system, and illustrating a coiled skeletal frame inserted within the sound tube and a small pressure vent incorporated on sound conduction tube lateral to the primary seal;

Fig. 16 shows a detailed view of a tubular insert also having only a primary seal, in which the primary seal comprises a cluster of two flanges;

Fig. 17 shows a completely in the canal (CIC) configuration of the invention;

Fig. 18 shows an electrically programmable version of the hearing device of the invention, the device being electrically connected to an external programmer, and with latchable reed switch controlled by an external control magnet in proximity to the device;

Fig. 19 shows a hearing device of the invention used for audio listening applications, with a main module comprising a receiver electrically connected to an external audio device;

Fig. 20 shows a test setup for Experiment B to study the acoustic effects of the dual seal system in terms of acoustic sealing and occlusion relief;

Fig. 21 shows the electrical schematics of a hearing device prototype constructed according to the present invention for studies described in Experiment C; and

Fig. 22 shows the acoustic response curve of the hearing device with and without the tubular insert of the present invention.

Detailed Description of the Preferred Embodiments and Methods

The invention provides a canal hearing device with a dual acoustic seal system for preventing oscillatory feedback while simultaneously channeling occlusion sounds away from the tympanic membrane (eardrum), thus minimizing occlusion effects.

In the preferred embodiments shown in **Figs. 4-5**, the canal hearing device **40** comprises a main module **50** and a tubular insert **70**. The main module **50** is positioned primarily in the cartilaginous region **11** of the ear. The tubular insert **70** comprises an elongated sound conduction tube **71**, a primary seal **80** medially positioned in the bony region **13**, and a secondary seal **90** laterally positioned in the cartilaginous region. The primary seal **80** and secondary seal **90** are hollow and generally cylindrical in shape. They are also soft and conforming for fitting comfortably and in a sealing manner within the ear canal **10**. The tubular insert **70** is removably attachable from the main module **50**. In the preferred embodiments of the invention, the tubular insert **70** is disposable.

The main module comprises a housing **59** containing typical hearing aid components including, but not limited to, microphone **51**, receiver **53**, receiver sound port **57**, battery **54**, signal amplifier **56** and device controls (e.g., volume trimmer, not shown) for controlling or adjusting functions of the hearing device. The sound conduction tube **71** conducts amplified sound from receiver sound port **57** to the tympanic membrane **18**.

The main module is positioned in the cartilaginous portion of the ear canal, either partially past the aperture of the ear canal (**Fig. 4**) or completely past the aperture medially (**Fig. 17**). However, the receiver section **58** of main module **50** is positioned in the

cartilaginous part of the ear canal past the aperture. The receiver section **58** has a diameter smaller than the ear canal **10**, thus making little or no contact at all with the wall of the ear canal.

The tubular insert **70** extends medially from the cartilaginous region **11** into the bony portion **13** of the ear canal. The sound conduction tube **71** has a diameter considerably smaller than that of the ear canal and is radially flexible for ease of insertion and for flexing during canal deformations associated with jaw movements. However, the sound conduction tube is axially sufficiently rigid to provide kink-resistance and torque ability for proper and consistent placement within the ear canal. In a preferred embodiment of the invention, the sound conduction tube **71** (**Fig. 5**) comprises a thin tubular sheath **73** and a skeletal frame **72** (e.g., coil) for achieving the desired radial and axial properties. Skeletal frame **72** is preferably composed of metal or metal alloy.

The primary seal **80** and secondary seal **90** are cylindrically hollow and coaxially concentrically positioned over the sound conduction tube **71**. The cross-sectional diameters of primary seal **80** and secondary seal **90** are substantially larger than the diameter of the sound conduction tube **71**, and the seals themselves are sufficiently spaced-apart, in order to provide a substantial range of conformability for improved comfort and acoustic sealing within the ear canal.

The primary seal **80** and the tympanic membrane **18** form a first chamber **85** (**Fig. 4**) of air-space therebetween. The primary seal **80** and secondary seal **90** form a second chamber **95** therebetween. The secondary seal **90**, although providing additional acoustic sealing

function for the prevention of oscillatory feedback, also has a relatively large vent **91**, compared to pressure vent **81** (**Figs. 4** and **5**) on the primary seal **80**. The large vent **91**, referred to herein as occlusion-relief vent, provides a path of least resistance for occlusion sounds **35** (**Fig. 4**) generated by the individual wearing the hearing device **40**.

The tubular insert **70** is removably connected to receiver section **58** and particularly receiver sound port **57** via an appropriate physical connection. In a preferred embodiment shown in **Fig. 5**, the tubular insert comprises a tube connector **74**, at the lateral end **78** of sound conduction tube **71**. The tube connector **74** slides sidewise into a receiver connector **42** in the direction shown by arrow **79**. The removal is similarly achieved by side-sliding the tubular insert in the opposite direction. A side-slide connection mechanism is advantageous for providing a secure connection and preventing accidental disconnection of the tubular insert while the device is being removed from the ear canal **10**.

The contact of the seals, particularly the primary seal **80** along the walls of the ear canal in the bony region, should span a length (**L** in **Fig. 5**) of at least 2 mm for an effective acoustic sealing within. This span is also necessary to distribute and minimize contact pressure for improved comfort. The seals should have rounded edges and smooth surfaces to provide a comfortable and effective acoustic sealing. For example, in **Figs. 4** and **5** the seals are essentially flanged or mushroom shaped as shown. However, the shape or configuration may be different while achieving equal or even improved effectiveness. In **Fig. 6** for example, the primary seal **80** is shaped with a rounded leading edge **82** and a lagging flange **83**. This combination is suitable for providing insertion comfort and effective sealing. The secondary seal

is shown alternatively with a pair of clustered flanged seals comprising a leading seal **92** and lagging seal **93**. The possibilities of seal designs and configurations are numerous, as will become obvious to those skilled in the art from the description herein.

The sound conduction tube **71** may be extended medially past the primary seal **80** as shown in **Fig. 5**. Tube extension **76** allows tube sound opening **77** to be in closer proximity to the tympanic membrane **18** for a more effective, energy efficient, and faithful sound reproduction. The tube extension **76** may comprise a rounded tip **75** to minimize the possibility of canal abrasion during insertion of the tubular insert in the ear canal.

The sound conduction tube **71** of the tubular insert **70** must be sufficiently narrow in diameter and elongated to achieve comfortable deep insertion into the bony region **13**. Furthermore, by appropriately selecting the appropriate ratio of diameter and length of the sound conduction tube **71**, the characteristics of sound delivered **31** (**Fig. 6**), particularly at high frequencies can be significantly improved. It has been determined by experiments (see, for example, Experiments B and C described below) that optimal performance of the tubular insert of the invention is achieved by sound conduction tube **71** having a length of at least 8 mm and a inside diameter (ID) range between 1 and 2 mm. The outside diameter (OD) is preferably less than 2.5 mm. The wall thickness of the sound conduction tube **71** is preferably less than .4 mm in order to ensure proper flexibility of the sound conduction tube.

The elongated tubular insert **70**, having a length of at least 8 mm, considerably reduces, if not completely eliminates, the problem of cerumen (earwax) build up on sound port **57** of the receiver. This is partially due to the length of the sound conduction tube **71** presenting a

substantial separation between the tube sound opening **77** and receiver sound port **57**. In addition, any presence or accumulation of cerumen within the sound conduction tube **71** will be disposed of as the user periodically discards the disposable tubular insert.

The occlusion-relief vent **91** of the secondary seal **90** may be in the form of a hole as shown in **Figs. 4** and **5**, or alternatively as a tube as shown in **Fig. 6**. The occlusion-relief vent **91** may be essentially provided as any conductive acoustic pathway connecting, directly or indirectly, the second chamber **95** with the outside of the ear (**Fig. 4**).

On the other hand, the pressure vent **81** associated with the primary seal, is provided primarily for air pressure equalization to prevent damage to the tympanic membrane. This equalization, shown by dual arrows **84** (**Fig. 4**), is required during device insertion or removal, or for changes in atmospheric pressures experienced in an airplane for example. The diameter of the pressure vent **81** must be very small so as to provide substantial sealing within the bony region of the ear canal. Holes of diameter less than .5 mm are known to have minimal acoustic impact in terms of leakage or modification of the acoustic response near the tympanic membrane. The pressure vent hole **81** may be directly incorporated within the primary seal as shown in **Figs. 4** and **5**. Alternatively, a miniature hole **81** (**Fig. 6**) along the tubing of the sound conductive tube **71** is equally effective as an indirect way to pressure vent the primary seal **80**. The pressure vent may also be in the form of a slit (**81** in **Fig. 12A**), cavity (not shown) or a tube (not shown). An actual vent hole for pressure venting may not be required if minute leakage is present across the primary seal. It is well known in the field of acoustics that minute leakages generally do not effect the acoustic conduction nor adversely cause oscillatory

feedback. For example, pressure vent leakage can be achieved by an air-permeable seal or by purposely designing an imperfect seal along the perimeter of the acoustic seal.

Regardless of the actual pressure venting employed, the occlusion-relief vent **91** must be substantially larger than pressure relief vent **81**. The occlusion-relief vent is preferably larger than 1 mm in diameter. The cross-sectional area of the occlusion-relief vent is preferably at least 3 times that of the pressure vent. This is necessary in order to provide a path of least resistance for occlusion sounds within the second chamber **95**. The substantial difference in acoustic impedance for the two venting systems may be achieved by other design means in addition to hole diameter. For example, by providing a plurality of smaller holes (not shown) or by adjusting the length of a vent tube (**91** in **Fig. 6**). Regardless of the venting method used, the acoustic impedance of the pressure vent must be substantially larger than that of the occlusion-relief vent, preferably by at least 10 decibels at frequencies below 500 Hz, which are the primary frequencies causing occlusion effect.

The relative magnitude of venting by the dual seal system of the present invention is important for achieving the desired occlusion relief. However, the accumulative sealing effect of the two seals, on the other hand, is also important for increasing the maximum gain or amplification of the hearing device **40** prior to reaching oscillatory feedback. This is also known as gain before feedback.

The main module must also provide means for ensuring proper occlusion relief venting as shown by arrows **35** and **35'** in **Figs. 4** and **6**. This venting may be accomplished by an actual device vent **23** (**Figs. 4** and **6**) or by an imperfect fit of the main module within the ear.

The connection mechanism between the tubular insert **70** and the receiver section **58** may be of any suitable configuration for providing a secure and effective connection. For example, **Fig. 6** shows an alternative connection with a nozzle as a receiver connector **42**, which is fitted directly within the lateral end **78** of the flexible sound conductive tube **71**. In yet another mating configuration, the tube connector **74** (**Fig. 7**) is fitted concentrically coaxially over the receiver section **58**. Other mating mechanisms (not shown) include threaded, snap-on and pressure-fit designs, or any combination of the above, as known by those skilled in the art of miniature mechanics.

In the embodiments shown in **Figs. 5** and **7**, the sound conduction tube **71** comprises a coiled skeletal frame **72**, which is inserted within a protective thin tubular sheet **73**. The coil provides desirable mechanical properties, radial and axial, such as being non-collapsible and kink-resistant, in response to torque and other forces as the sound conduction tube **71** is being inserted in the ear canal. This is important in order to minimize adverse acoustic effects on output sound (**30** and **31** in **Fig. 6**) as it travels medially within the sound conduction tube towards the tympanic membrane **18**.

The desired mechanical properties of the sound conduction tube **71** may be alternatively achieved by incorporating circular support elements **87** and longitudinal support elements **88** as shown in **Fig 8**. These support elements may be molded of the same material used in the fabrication of the tubular sheath **73** or may be of different material molded within the tubular sheath **73**. The combination of these support elements can be numerous and includes helical support elements (**89** in **Fig. 9**), braided element (not shown) and other configurations known

by those skilled in the art of tube and catheter designs.

The sound conduction tube **71** may comprise more than one tube, i.e. multilumen, for conducting multiple sound channels for separately conducting occlusion sounds **35**. For example, **Fig. 10** shows a sound conduction tube **71** having three channel paths (**37**, **38** and **39**). Each channel may be optimized to achieve a desired acoustic effect such as filtering or high frequency boosting as commonly known in the field of hearing aid acoustics design. **Fig. 11** shows sound conduction tube **71** with two channels **45** and **46**. The first channel **45** conducts output sounds **30**, **31**, medially toward the tympanic membrane. The second channel **46** is blocked by a medial wall **86** on its medial end. However, second channel **46** incorporates an occlusion-relief vent **91**, which allows occlusion sounds to substantially leak out as shown by arrows **35** and **35'**.

The tubular insert **70** is preferably made, at least partially, of rubber or rubber-like material, such as silicone, in order to provide the desired mechanical and acoustic characteristics. These materials are generally durable, inexpensive and easy to manufacture. Other suitable material includes foam and other polymers, which can also be formed into tubular shapes (for the sound conduction tube) and cylindrically hollow shapes (for the seals).

The cross sectional perimeter shape of primary or secondary seal may be circular (**Fig. 12A**), elliptical (**Fig. 12B**) or oval and inferiorly pointed (**Fig. 12C**) for matching the cross-sectional diameter of the typical ear canal. The seals must be flexible to comfortably conform to the shape of the ear canal while providing the necessary acoustic sealing.

The seals may incorporate a lubricant material (not shown), particularly along the

contact surface, to further facilitate insertion and removal within the ear canal. The seals may also be treated with medication material to minimize possible contamination and infections within the ear canal. The medication may include anti-bacterial, anti-microbial and like agents, for example.

Due to variations in canal size and shape across individuals, the tubular insert **70** is preferably provided in assorted generic sizes in order to properly fit the vast majority of individuals without resorting to any custom fabrication. An experiment to study the range of canal sizes, particularly the diameters was conducted as explained below in the section titled Experiment A.

The main module **50** of the preferred embodiment is fitted inconspicuously in medial end of the concha cavity **2**, which is behind the tragus notch (not shown). Concha cavity placement (see **Figs. 4** and **13**) is also especially desirable for persons of limited manual dexterity because it is relatively accessible for insertion and removal. The receiver section **58** extends medially into the ear canal past the aperture **17**. A handle **41** may be used to further facilitate insertion and removal. The housing **59** of the main module **50** must be rigid for durable protecting of the enclosed components.

The main module is preferably universal in shape (generic) to fit the vast majority of ears in the concha cavity **2**. This is possible for at least three reasons. First, the exact fit of the main module in the ear is not critical since sealing is primarily achieved by the primary seal **80**, and to a lesser extent by the secondary seal **90**. Second, the concha cavity, at its medial end, generally has a generic funnel-like shape. Third, the ear at the concha cavity area is relatively

flexible thus somewhat conforms to the rigid housing **59** of the main module **50** when inserted within.

In the embodiment of **Fig. 13**, the main module **50** makes no contact at all with the walls of the ear. The main module **50** is essentially suspended by the secondary seal **90**, which provides physical support for the main module as well as the sound conduction tube as shown in **Fig. 13**. The substantial clearance between the housing **59** of the main module **50** and the walls of the ear allow occlusion sounds **35** from the occlusion relief vent **91** to freely exit as shown. This eliminates the need for a separate vent within main module **50** as is the case in the above embodiments shown in **Figs. 4, 6** and **7**. A pressure vent **81**, associated with venting the primary seal **80**, is alternatively positioned within receiver connection **42 (Fig. 13)**.

In yet another alternate embodiment of the invention the dual seal system is distributed between a primary seal within a tubular inset and a secondary seal within the main housing as shown in **Figs. 14-17**. In these embodiments, the tubular insert **70** comprises only a primary seal **80** for positioning in the bony region **13**. The secondary seal is provided by housing of the main module, which is fitted in a sealing manner within the ear. This is possible because the medial concha area has a generic shape as mentioned above. The secondary seal of the main module provides the additional required sealing for the prevention of oscillatory feedback. Similarly, the primary seal **80** and the tympanic membrane **18** form a first chamber therebetween. The second chamber **95** is formed between the main module **50** and the primary seal **80**. An occlusion-relief vent **23** within main module **50** provides a path of least resistance for occlusion sounds **35**.

Fig. 15 shows a mushroom shaped primary seal **80** with pressure vent **81**, tube connector **74**, tubular sheath **73**, and coil **72**.

Fig. 16 shows a primary seal **80** in clustered dual flange configuration with a medial flange **47** and a lateral flange **48**.

The main module may be fitted completely in the ear canal medially past the aperture **17** as shown in **Fig. 17**. This embodiment, representing a CIC hearing configuration, comprises a tubular insert **70** with a primary seal **80** well into the bony region **13**. The tubular insert **70** is connected to main module **50** via receiver connector **42**. A relatively long handle **41** is provided to facilitate insertion and removal of the CIC hearing device **40**. An occlusion-relief vent **23** is incorporated within main housing **50** for providing a path of least resistance compared with the pressure vent **81** on the sound conduction tube **71** for pressure venting of the primary seal **80**.

The secondary seal, whether part of a tubular insert **70** (**Figs. 4-7**), or part of main module **50** (**Fig. 14-17**), presents a barrier for external unamplified sounds thus attenuating and interfering with unamplified sounds when entering the ear canal. However, this invention is not concerned with allowing unamplified sounds to enter the ear canal; instead, the concern here is to seal amplified sounds delivered near the tympanic membrane while providing significant occlusion relief.

The hearing device **40** of the present invention may be manually adjusted with manual controls (not shown) as well known in the field of hearing aid design. The hearing device **40** may also be electrically programmable also well known as shown in **Fig. 18**. A programmable

hearing device typically comprises a programmable connector **43** for receiving electrical signals from a programming plug **91** connected via a cable **92** to a programming device **90**. The programming device **90** is typically incorporated within a computer system (not shown). The main housing **50** comprises a battery door **55** and occlusion relief vent **23**. The programming and control of hearing devices may be wireless (not shown) via radio frequency (RF), ultrasound, infrared (IR), electromagnetic (EM) or other methods as widely known in the field of wireless hearing aid programming.

The main module may comprise a reed-switch **95** (**Fig. 18**) with a latching magnet **96** for remote control by a control magnet **97**. The reed-switch **95** can be used to turn on/off the hearing device or to adjust one or more parameters of the hearing device. The control magnet **97** is shown in the shape of a bar with south **99** (S) and north **98** (N) magnetic polarities across its length. The user selects one side or the other for switching the device ON or OFF as desired.

The hearing devices of the above embodiments are suitable for use by hearing impaired individuals. However, the unique characteristics of the dual seal system may be equally applicable for audio and other communication applications. For example, **Fig. 19** shows a hearing device **100** for audio applications comprising a main module **110** and a replaceable tubular insert **70**. The tubular insert comprises a primary seal **80** and a sound conduction tube **71** with skeletal frame **72** within. The primary seal **80** ensures energy efficient reproduction of sound, particularly at high frequencies, near the tympanic membrane. The main housing **110** comprises an occlusion-relief vent **23** for leaking out occlusion sounds **35** to the outside of the

ear (arrow 35'). In this application, the main module **110** essentially contains a receiver **52**, which is connected via electrical wires **111** within electrical cable **112** to an audio device **115** external to the ear. Similarly, the hearing device for audio applications may be wirelessly connected to an external audio device via the appropriate wireless communication method (not shown).

Experiment A.

In a study performed by the applicants herein, the cross-sectional dimensions of ear canals were measured from 10 canal impressions obtained from adult cadaver ears. The long (vertical) and short (horizontal) diameters, D_L and D_S respectively, of cross sections at the center of the cartilaginous region **11** and bony region **13** were measured and shown in Table 1 below. The diameters where measured across the widest points of each cadaver impression at each of the two regions. All measurements were taken by a digital caliper (model CD-6"CS manufactured by Mitutoyo). The impression material used was low viscosity Hydrophilic Vinyl Polysiloxane (manufactured by Densply/Caulk) using a dispensing system (model Quixx manufactured by Caulk).

Table 1.

Sample #	Cartilaginous Region Diameters in mm		Bony Region Diameters in mm	
	Short (D_S)	Long (D_L)	Short (D_S)	Long (D_L)
1-R	7.8	10.3	8.0	10.5
1-L	7.8	11.9	8.1	11.2
2-R	3.8	8.9	4.2	8.9
2-L	5.3	8.1	4.3	8.6
3-R	5.5	6.3	5.0	7.7
3-L	4.9	6.5	4.9	7.3
4-R	6.9	9.2	6.7	10.4
5-R	6.9	9.2	7.5	9.5
5-L	6.8	8.2	7.5	8.7
7-L	6.3	7.0	4.9	6.7
Average	6.2	8.6	6.1	9.0

Results and Conclusion

The diameter dimensions of the ear canal vary significantly among adult individuals. In general, variations occur more so across the short diameters (D_S). Although not apparent from the above measurements, the cartilaginous region is fleshy and thus somewhat expandable across the short diameter D_S. Based on the above measurements, a diameter of 2.5 mm (OD) or less for the sound conduction tube **71** was determined to be optimal for comfort of insertion. The cross sectional diameter of an assorted set of generic conforming primary seals, oval in design as shown in **Fig. 12C**, were selected according to above measurements as shown in Table 2 below.

Table 2

Primary Seal Size	Short Diameter (D_S) in mm	Long Diameter (D_L) in mm
Small	4.8	7.9
Medium	6.0	9.9
Large	8.2	13.6

Experiment B

The dual seal concept in relation to acoustic sealing (attenuation) and occlusion effects was simulated in a setup shown in **Fig 20**. A test cavity **120**, simulating an ear canal and a concha cavity, was produced from a cut section of a syringe. The test cavity **120** had a volume of 1.5 cubic centimeters (cc) with markings indicating the gradual volume within. The test cavity **120** had a lateral opening **121** and a medial opening **123** terminated by a thin diaphragm **123** simulating an eardrum. The test cavity had an ID of approximately 8.5 mm and length of about 27 mm.

The setup comprised a first receiver **R1** (a speaker- model EH-7159 manufactured by Knowles Electronics of Itasca, IL) for producing acoustic sounds simulating a receiver **53** (**Figs. 4** and **6**) of a hearing aid, and a second receiver **R2** (also model EH-7195) for producing sounds simulating occlusion sounds **35** (**Figs. 4** and **6**). The receivers **R1** and **R2** were connected to a signal generator (**SG**) incorporated within a spectrum analyzer (**SA**), model SRS-780 manufactured by Stanford Research Systems.

A primary seal **124** and secondary seal **125** were fabricated of rubber having a sealing

contact along the inside wall of the test cavity **120** spanning a length of approximately 3.4 mm. The primary seal **124** and diaphragm **123** formed a first chamber or space **S1**. The primary seal **124** and secondary seal **125** formed a second chamber or space **S2**. Medial to the secondary seal **125**, a third open space **S3** is formed simulating the concha cavity **2** of an ear. The primary seal **124** was inserted medially past the .5 cc marking in order to simulate a deep positioning within the bony region of an ear canal. The secondary seal **125** was inserted medially past the 1.0 cc marking which roughly simulates the aperture of an ear canal.

A sound conduction tube **T2**, of approximately 13 mm in length and 1.5 mm ID, connected **R1** receiver to the first space **S1** as shown. An occlusion relief vent in the form of a tube **T3**, connected the second space **S2** to third space **S3**. **T3** had an ID of approximately 1.5 mm and length of 5 mm. A pressure vent **T1**, also in the form of a tube, measured .5 mm in ID and 3.5 mm in length. Based on the above dimensions, the cross sectional area of the occlusion relief vent **T3** was approximately 9 times that of pressure vent **T1**.

The sound pressure level, or response, produced by either receiver (**R1** or **R2**) was measured at **S1**, **S2** and **S3** spaces by probe tubes **PT1**, **PT2** and **PT3**, respectively. The thin probe tubes were inserted in holes drilled in the syringe as shown in **Fig. 20**. Depending on the measurement, each probe tube was connected to probe tube measuring system **130** (model ER-7C, manufactured by Etymotic Research) consisting of probe microphone **131** and amplifier **132**. Probe microphone **131** is shown connected to probe tube **PT2**. The probe tube measuring system **130** was also connected to the spectrum analyzer **SA** with results shown on its display **D**.

A thin plastic sheet of approximately .08 mm thickness was used for the construction of test diaphragm **123**. The test diaphragm **123** was placed in a sealing manner over the medial opening **122** via a holding ring **127** as shown.

A chirp signal comprising equal amplitude of sinusoidal components between 125 to 4,000 Hz was used to measure response data in the range of standard audiometric frequencies.

It is important to note here that the test cavity **120** and diaphragm **123** represent only a crude model of the ear canal **10** and tympanic membrane **18**. The experiment was merely designed to demonstrate the general effect of the dual seal concept as relating to sealing and occlusion. Actual results perceived by humans are likely to be different and varying according to the unique anatomy and physiology of each individual.

Referring to Table 3 below, the difference in the acoustic response of **R1** measured by **PT1** and **PT2** represents the acoustic attenuation provided by the primary seal alone. The difference in the response between **PT1** and **PT3** represents the total acoustic attenuation. This includes not only the accumulative attenuation of the two seals, but also the effect of sound dispersion in the open cavity of **S3**. This simulated the leakage with respect to a microphone of the hearing device, which also resides laterally towards the open space of a concha cavity.

Table 3

R1 Response in dB SPL	125 Hz	250 Hz	500 Hz	1000 Hz	2000 Hz	3000 Hz	4000 Hz
@ PT1	56.4	66.6	71.8	70.0	68.3	70.9	74.7
@ PT2	34.0	47.8	56.0	58.7	60.0	58.7	58.1
@ PT3	22.7	26.3	30.3	34.0	40.3	43.6	47.0
Primary seal atten. (dB)	22.4	18.8	15.8	11.3	8.3	12.2	16.6
Total atten. (dB)	33.7	40.3	41.5	36.0	28.0	27.3	27.7

Referring to Table 4, below, the difference in acoustic responses of **R2** measured by **PT1** and **PT2** represents the occlusion sound attenuation provided by the primary system. The difference in the acoustic responses of **R2** measured by **PT1** and **PT3** is indicative of occlusion relief provided by the two seal system. For **R2** response measurement at **PT3**, the lateral cavity **S3** was closed in order to more accurately measure the magnitude of leaked occlusion sound (**35'** in **Fig. 4**) prior its dispersion.

Table 4

R2 Response in dB SPL	125 Hz	250 Hz	500 Hz	1000 Hz	2000 Hz	3000 Hz	4000 Hz
@ PT1	23.1	31.7	46.5	48.9	45.2	43.7	42.6
@ PT2	30.5	42.2	52.7	60.4	71.1	76.9	70.7
@ PT3	47.6	52.4	54.7	61.4	67.4	69.7	58.2
Primary seal occlusion block (dB)	7.4	10.5	6.2	11.5	25.9	33.2	28.1
Total occlusion relief (dB)	24.5	20.7	8.2	12.5	22.2	26	15.6

Results and Conclusion

Referring to Table 3 above, the attenuation (sealing) of the dual seal system was significantly higher than that of the primary seal alone even with the presence of a large vent associated with the secondary seal. The attenuation improvement occurred at all frequencies including higher frequencies, which are the primary frequencies causing oscillatory feedback in hearing aid use.

Referring to the Table 4 above, the occlusion relief was also significantly improved by the dual seal system, particularly for frequencies below 500 Hz, which are the primary frequencies causing occlusion effect in hearing aid use.

Experiment C

The acoustic conduction advantage, particularly high frequency boosting, of the tubular insert was tested according to the following experiment.

A prototype of the canal hearing device according to the embodiment of **Fig. 4** was fabricated. The electroacoustic circuit of **Fig. 21** was implemented with a miniature microphone/amplifier **M** (model FI-3342 manufactured by Knowles Electronics of Itasca, IL), class-D receiver **R** (model FS3379 also manufactured by Knowles Electronics) and miniature 450K Ohm volume trimmer $\mathbf{R_G}$ (model PJ-62 manufactured by Microtronics A/S of Denmark). Volume trimmer $\mathbf{R_G}$ was connected across the output terminal and the Feedback terminal **FB** of microphone **M**. Miniature capacitors **C1** and $\mathbf{C_2}$ with values of .01 uF and 2.2 uF, respectively were employed. A reed switch assembly (**RS**) employing a miniature reed-switch

(model HSR-003DT, manufactured by Hermetic Switch, Inc. of Chickasha, OK.) and a miniature Neudymium Iron Boron (NdFeB) magnet (**96** in **Fig. 18**) were used for providing a latchable switch. The switch was remotely activated (on/off) by a control magnet in the shape of a bar as described above.

The tubular insert used comprised a sound conduction tube made of a silicone tube 15.6 mm in length, 2.4 mm OD and 1.58 mm ID. A metal coil was inserted in the sound conduction tube. The coil was approximately 13 mm in length, 1.61 mm OD and 1.49 mm ID.

The acoustic response of the prototype device for 60 dB SPL (sound pressure level) sinusoidal sweep was measured by standard hearing aid analysis methods employing a standard CIC coupler (Manufactured by Frye Electronics) and hearing aid analyzer (model Fonix 5500-Z also manufactured by Frye Electronics). The response curve was plotted (**Fig. 22**) with and without tubular insert (dotted line labeled "With 15.6 mm tubular insert", solid line labeled "Without tubular insert").

Results and Conclusion

Referring to **Fig. 22**, the tubular insert provided a significant boost in the acoustic response for frequencies greater than 500 Hz. The increase was particularly significant in the frequency range between 4 khz and 6 khz, reaching as much as 8 decibels. Similar experiments conducted by the inventors showed an increase at certain frequencies reaching as much as 14 decibels.

Although presently contemplated best modes of practicing the invention have been described herein, it will be recognized by those skilled in the art to which the invention pertains from a consideration of the foregoing description of presently preferred and alternate embodiments and methods of fabrication thereof, that variations and modifications of these exemplary embodiments and methods may be made without departing from the true spirit and scope of the invention. Thus, the above-described embodiments of the invention should not be viewed as exhaustive or as limiting the invention to the precise configurations or techniques disclosed. Rather, it is intended that the invention shall be limited only by the appended claims and the rules and principles of applicable law.